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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,982	10/01/2003	Philip A. Beachy	JHU1510-2	9078

7590 12/13/2004

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/677,982

Applicant(s)

BEACHY ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to isolated transcription factor, classified in class 530, subclass 350.
- II. Claims 4-25, drawn to method for modulating expression of a target gene by modulating phosphorylation, classified in class 435, subclass 375.
- III. Claims 26-30, drawn to method for modulating proliferation or differentiation, classified in class 435, subclass 375.
- IV. Claims 31-34, drawn to method for treating a cell proliferative disorder by administering a phosphatase inhibitor, classified in class 514, subclass 1.
- V. Claim 35, drawn to method for inhibiting bone defects in a subject, classified in class 514, subclass 1.
- VI. Claims 36-37, drawn to method for diagnosing a subject, classified in class 435, subclass 7.1.
- VII. Claims 38-45, drawn to a method for identifying a compound that inhibits a phosphatase by measuring

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expression of a target gene, classified in class 435, subclass 29.

VIII. Claim 46, drawn to method for identifying a compound that affects a hedgehog signaling pathway by measuring phosphorylation, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used in a materially different process of using, making antibodies to be used to detect the presence of the protein in assays, or for making phosphorylated protein to be used in other assays.

Inventions of Group I and Groups II-VI and VIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The isolated transcription factor of Group I is not used in or made

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by the methods of Groups II-VI and VIII. The operation, function and effects of the isolated transcription factor of Group I is different and distinct from the operation, function and effects of the methods of Groups II-VI and VIII. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups II-VIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II-VIII comprise steps which are not required for or present in the methods of the other groups: modulating expression of a target gene by modulating the phosphorylation of a transcription factor which interacts with a response element operatively associated with the target gene (Group II), modulating proliferation or differentiation by modulating expression of a gene that modulates proliferation or differentiation by modulating the phosphorylation of a transcription factor which interacts with a response element operatively associated with the gene (Group III), treating a cell proliferative disorder in a subject by administering a phosphatase inhibitor (Group IV), inhibiting bone defects in a subject by modulating expression of a gene that mediates bone development by modulating the phosphorylation of a transcription factor which interacts with a response

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element operatively associated with the gene (Group V), diagnosing a midline defect by determining the level of phosphorylated transcription factor (Group VI), identifying a compound that inhibits a phosphatase by incubating the compound with the transcription factor and a phosphatase and detecting the effect on expression of the target gene (Group VII), and measuring the ability of a compound to affect HH signaling pathway by detecting the ability of the compound to affect the phosphorylation state of the transcription factor (Group VIII). The end result of the methods are different. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for Groups II, IV, and VI are not required for Groups III, V, and VIII, especially with regard to the non-patent literature search because each invention comprises step(s) that are not present in the methods of the other groups, even if otherwise classified in the same subclass, restriction for examination purposes as indicated is proper.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **Conclusion**

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should



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be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

December 10, 2004